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TRANSMITTAL LETTER TO THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)
CONCERNING A FILING UNDER 35 U.S.C. 371

741890-0023

U.S. APPLICATION NO. (if known, see 37 CFR 1.5)

Not Yet Assigned 10/048165

INTERNATIONAL APPLICATION NO.

PCT/IE00/00093

INTERNATIONAL FILING DATE

July 28, 2000

PRIORITY DATE CLAIMED

July 30, 1999

TITLE OF INVENTION A SURIGAL ACCESS DEVICE

APPLICANT(S) FOR DO/EO/US Martin CALDWELL and Christopher CUMMINS

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☒ This is an express request to promptly begin national examination procedures (35 U.S.C. 371(f)).
4. ☐ The US has been elected by the expiration of 19 months from the priority date (PCT Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2)) (**WO 01/08563 A2**)
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☒ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information:
 - 1.) International Preliminary Examination Report w/Amended Claims and Sheets
 - 2.) Twelve (12) Sheets of Drawings (Figs. 1-24)
 - 3.) Application Data Sheet

NVA213355.1

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10/048165
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APPLICATION INFORMATION

Title Line One:: A SURGICAL ACCCESS DEVICE
Total Drawing Sheets:: 12
Formal Drawings?:: Yes
Application Type:: Utility
Docket Number:: 741890-0023
Secrecy Order in Parent Appl.?:: No

REPRESENTATIVE INFORMATION

Registration Number One:: 32815
Registration Number Two:: 35483
Registration Number Three:: 38285
Registration Number Four:: 24312
Registration Number Five:: 27997

PRIOR FOREIGN APPLICATIONS

Foreign Application One:: S990659

2004515-1000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re **NATIONAL PHASE** Application of)
Martin CALDWELL et al) Attn: US/DO/EO
International Application No. PCT/IE00/00093)
International Filing Date: July 28, 2000)
For: A SURGICAL DEVICE) Date: January 29, 2002

PRELIMINARY AMENDMENT

Commissioner for Patents

Washington, D.C. 20231

Sir:

Please preliminarily amend the subject application as follows:

IN THE CLAIMS:

Please note, the amended claims are presented below in their amended form. Further, as an Attachment to the Amendment the amendments to the claims are outlined using the conventional method of bracketing and underlining.

PLEASE AMEND THE FOLLOWING CLAIMS 5, 6, 9, 10, 13, 17, 19 and 22-25 from the Amended Preliminary Examination Report Claims)

5. **(AMENDED)** A surgical device (1) as claimed in claim 1, wherein the trocar (5) incorporates guard means for preventing injury to the surgeon.

6. **(AMENDED)** A surgical device (1) as claimed in claim 1, wherein the cannula (6) incorporates means (15) for releaseably attaching the cannula to an interior (3) of the body cavity.

9. **(AMENDED)** A surgical device (1) as claimed in claim 1, wherein the cannula (6) incorporates a valve to prevent loss of gas from the body cavity when the cannula is in position.

10. **(AMENDED)** A surgical device as claimed in claim 1, wherein the fixing means incorporates an anchor ring (7) formed for releasable engagement with a proximal end of the cannula (6) extending from the body when the cannula (6) is in position in the body cavity.

13. **(AMENDED)** A surgical device as claimed in claim 1, incorporating an external seal (901) and an internal valve (902), the seal (901) and valve (902) being mounted about opposing ends of the cannula (6)

17. **(AMENDED)** A surgical device as claimed in claim 13, wherein the seal housing (901) defines an extended entry port (904).

19. **(AMENDED)** A surgical device as claimed in claim 1 wherein the cannula (6) incorporates an insufflation port (910).

22. **(AMENDED)** A surgical device as claimed in claim 11, wherein the anchor ring (7) incorporates cushion means to prevent trauma to the body cavity wall and ensure a gas tight seal.

23. **(AMENDED)** A surgical device as claimed in claim 11, wherein the distal ring (15) incorporates cushion means to prevent trauma to the body cavity wall and ensures a gas tight seal.

24. **(AMENDED)** A surgical device as claimed in claim 1, incorporating a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to being fixed in position on a patient.

25. **(AMENDED)** A surgical device as claimed in claim 1, incorporating an adjustable pressure release valve.

PLEASE ADD THE FOLLOWING NEW CLAIMS 26-37:

26. **(NEW)** A method for insertion of a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula defining a conduit into the body cavity;

a trocar carried on the cannula and formed for piercing or cutting tissue to position the cannula; and

fixing means for removably securing the cannula in position on the patient during surgery,

the method comprising the steps of inserting the trocar into the body cavity through the access port, cutting or piercing tissue outwardly from within the body cavity using the trocar out to an operating site and inserting a cannula in the incision made using the trocar.

27. **(NEW)** A surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patients body, the device being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing means for removably securing the cannula in position on the patient during surgery, the

fixing means in turn having at least one seal, at one seal being movable along or about a longitudinal axis of the cannula to secure the device in position.

28. (NEW) A surgical device as claimed in claim 27, in which the fixing means is provided by:

an inner seal having an upwardly extending conduit carried on an internal mounting ring; and

an external seal having a downwardly extending conduit carried on an external mounting ring, the upwardly and downwardly extending conduits being formed for releasable engagement when in position on a patient to define the cannula.

29. (NEW) A surgical device as claimed in claim 28, wherein the conduits are formed for slidable interengagement.

30. (NEW) A surgical device as claimed in claim 27 or 28, in which the conduits incorporate a ratchet retainer.

31. (NEW) A surgical device as claimed in claim 30, wherein each conduit is deformable to facilitate removal by disengaging the ratchet retainer.

32. (NEW) A surgical device as claimed in [any of claims 30 to 33] claim 28, wherein the, each mounting ring has an associated pressure absorption and seal enhancement means.

33. (NEW) A surgical device as claimed in [any of claims 30 to 34] claim 28, wherein the cannula incorporates a valve.

34. (NEW) A surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an

incision in a patients body, the device being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing means for removably securing the cannula in position on the patient during surgery provided by an external and an internal mounting ring, one or both rings being pivotally movable about a longitudinal axis of the cannula.

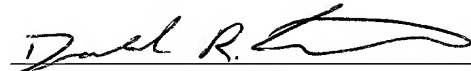
35. **(NEW)** A surgical device as claimed in claim 36, in which the cannula is collapsible under pressure from one or both mounting rings to secure the cannula in position.
36. **(NEW)** A surgical device as claimed in claim 35, in which the cannula is provided by a section of pleated tubing carried on the device.
37. **(NEW)** A surgical device as claimed in claim 36, wherein the external mounting ring defines an entry funnel having an oversize entry aperture for receiving and facilitating insertion of a piece of medical equipment.

REMARKS

The claims have been amended to correct the improper multiple dependencies in order to place them in better condition for examination. The foregoing amendments being carried out with respect to the claims set forth in the International Preliminary Examination Report dated November 29, 2001. Additional, claims 26-37 have been added and correspond to claims 28-39 of the originally filed International Application.

Examination on the merits is requested.

Respectfully submitted,



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DRS/JLC/sas

VERSION WITH MARKINGS TO SHOW CHANGES MADE**IN THE CLAIMS:****PLEASE AMEND THE FOLLOWING CLAIMS:****PLEASE AMEND THE FOLLOWING CLAIMS 5, 6, 9, 10, 13, 17, 19 and 22-25 from the Amended Preliminary Examination Report Claims)**

5. (AMENDED) A surgical device (1) as claimed in [any preceding claim] claim 1, wherein the trocar (5) incorporates guard means for preventing injury to the surgeon.

6. (AMENDED) A surgical device (1) as claimed in [any preceding claim] claim 1, wherein the cannula (6) incorporates means (15) for releaseably attaching the cannula to an interior (3) of the body cavity.

9. (AMENDED) A surgical device (1) as claimed in [any preceding claim] claim 1, wherein the cannula (6) incorporates a valve to prevent loss of gas from the body cavity when the cannula is in position.

10. (AMENDED) A surgical device as claimed in [any preceding claim] claim 1, wherein the fixing means incorporates an anchor ring (7) formed for releasable engagement with a proximal end of the cannula (6) extending from the body when the cannula (6) is in position in the body cavity.

13. (AMENDED) A surgical device as claimed in [any preceding claim] claim 1, incorporating an external seal (901) and an internal valve (902), the seal (901) and valve (902) being mounted about opposing ends of the cannula (6)

17. **(AMENDED)** A surgical device as claimed in [any of claims 13 to 16] claim 13, wherein the seal housing (901) defines an extended entry port (904).

19. **(AMENDED)** A surgical device as claimed in [any preceding claim] claim 1 wherein the cannula (6) incorporates an insufflation port (910).

22. **(AMENDED)** A surgical device as claimed in [any of claims 11 to 21] claim 11, wherein the anchor ring (7) incorporates cushion means to prevent trauma to the body cavity wall and ensure a gas tight seal.

23. **(AMENDED)** A surgical device as claimed in [any of claims 11 to 22] claim 11, wherein the distal ring (15) incorporates cushion means to prevent trauma to the body cavity wall and ensures a gas tight seal.

24. **(AMENDED)** A surgical device as claimed in [any preceding claim] claim 1, incorporating a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to being fixed in position on a patient.

25. **(AMENDED)** A surgical device as claimed in [any preceding claim] claim 1, incorporating an adjustable pressure release valve.

PLEASE ADD THE FOLLOWING NEW CLAIMS 26-37:

26. **(NEW)** A method for insertion of a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula defining a conduit into the body cavity;

a trocar carried on the cannula and formed for piercing or cutting tissue to position the cannula; and

fixing means for removably securing the cannula in position on the patient during surgery,

the method comprising the steps of inserting the trocar into the body cavity through the access port, cutting or piercing tissue outwardly from within the body cavity using the trocar out to an operating site and inserting a cannula in the incision made using the trocar.

27. **(NEW)** A surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patients body, the device being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing means for removably securing the cannula in position on the patient during surgery, the

fixing means in turn having at least one seal, at one seal being movable along or about a longitudinal axis of the cannula to secure the device in position.

28. **(NEW)** A surgical device as claimed in claim 27, in which the fixing means is provided by:

an inner seal having an upwardly extending conduit carried on an internal mounting ring; and

an external seal having a downwardly extending conduit carried on an external mounting ring, the upwardly and downwardly extending conduits being formed for releasable engagement when in position on a patient to define the cannula.

29. **(NEW)** A surgical device as claimed in claim 28, wherein the conduits are formed for slidable interengagement.

30. (NEW) A surgical device as claimed in claim 27 or 28, in which the conduits incorporate a ratchet retainer.
31. (NEW) A surgical device as claimed in claim 30, wherein each conduit is deformable to facilitate removal by disengaging the ratchet retainer.
32. (NEW) A surgical device as claimed in [any of claims 30 to 33] claim 28, wherein the, each mounting ring has an associated pressure absorption and seal enhancement means.
33. (NEW) A surgical device as claimed in [any of claims 30 to 34] claim 28, wherein the cannula incorporates a valve.
34. (NEW) A surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patients body, the device being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing means for removably securing the cannula in position on the patient during surgery provided by an external and an internal mounting ring, one or both rings being pivotally movable about a longitudinal axis of the cannula.
35. (NEW) A surgical device as claimed in claim 36, in which the cannula is collapsible under pressure from one or both mounting rings to secure the cannula in position.
36. (NEW) A surgical device as claimed in claim 35, in which the cannula is provided by a section of pleated tubing carried on the device.

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A SURGICAL DEVICE

5 The present invention relates to a surgical device and more particularly to a trocar and cannula for use in minimally invasive surgery of the type using patient pneumoperitoneum and an access port.

10 Minimally invasive surgery of this type is carried out having introduced gas into a patient's body cavity through an incision and having sealed the incision with an access port. The access port enables hand assisted laproscopic surgery (HALS) or instrument assisted surgery to be performed. When the surgery requires the use of a second set of instruments, a trocar is often used to introduce a cannula as an alternative to a second incision and access port. A trocar is a surgical device designed to provide a small conduit known as a
15 cannula through tissue to allow instruments such as an endoscope to be inserted into the body cavity.

20 The uses of trocar and cannula devices have a number of problems generally. Previously known cannulas are prone to allowing gas to escape from the body cavity when in position. The gas may escape through the cannula while a surgical instrument is in use or from around the incision. The provision of a suitable seal is essential in maintaining the correct pressure of gas within the body cavity, however, it is also essential to ensure that the seal is provided in a manner which does not limit a surgeon's mobility or cause unnecessary trauma. This can prove particularly problematic where the device is to be inserted in a narrow portion of the body cavity. Existing cannulas are also prone to being ejected from
25 the body cavity due to gas pressure or instrument removal force, which is obviously unacceptable.

30 Additionally, fixing the cannula, once successfully in position, has presented difficulties. If the fixing arrangement is too large it can limit a surgeon's mobility and if the arrangement extends too far into the cavity there is a risk of unnecessary trauma. Furthermore, the insertion of the trocar often inadvertently causes unacceptable damage to a patient's tissue and internal organs.

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European Patent Specification No. EP 0 542 428 discloses a surgical trocar assembly for insertion of a laparoscopic instrument through an inner abdominal wall. A sleeve is provided which can be expanded within the abdominal cavity to abut against the surface of the abdominal wall to hold the sleeve in place, in combination with insulation to

5 electrically insulate the trocar assembly from the patient while the instrument is within the trocar assembly.

United States Patent Specification No. US 5,658,306 discloses a method for locating additional cannulae in surgery on a patient with the use of a guide member having proximal and distal extremities, comprising introducing the distal extremity of the guide member

10 through the skin of the body to a first location in the body. The distal extremity of the guide member is advanced in a direction below the skin to a second location remote from the first location. The distal extremity of the guide member is advanced through the skin of the patient at the second location from within the body to a position outside the body so

15 that the distal extremity is exposed outside the body. A cannula is placed over the distal extremity of the guide member and is advanced through the skin of the patient at the second location utilizing the guide member as a guide. The distal extremity of the guide member is then removed from the cannula.

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It is an object of this invention to provide a method and apparatus for inserting and using a cannula, which will overcome the aforementioned problems.

It is a further object of the invention to provide a method and apparatus for securing and using a cannula, which will overcome the aforementioned problems and which will reduce the risk of secondary seeding of cancerous cells at port sites.

Accordingly, there is provided a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula defining a conduit into the body cavity;

a trocar carried on the cannula and formed for piercing or cutting tissue to position the cannula; and

fixing means for removably securing the cannula in position on the patient during surgery,

characterised in that the trocar is removably mounted on the cannula, with the trocar providing a gas-tight cap for the cannula when the trocar is mounted on the cannula thereby enabling the trocar to be inserted into the body cavity through the access port and to cut or pierce tissue outwardly from within the body cavity out to an operating site, with no escape of gas from the body cavity;

In this way accidental damage to the patient's tissue or organs is prevented as the cutting or piercing point of the trocar is directed away from the patient's body during the fixing procedure.

Ideally, the device is formed for insertion into the body cavity through the access port and for cutting or piercing tissue outwardly from within the body cavity out to an operating site. Thus, the action of the trocar piercing the body cavity wall automatically draws the cannula into position.

Preferably, the trocar is removably mounted on the cannula.

In a particularly preferred embodiment, the trocar and cannula are connected with complementary engageable short threads on the trocar and cannula, such as quarter turn
5 threads.

Since the trocar is formed to provide a gas-tight cap for the cannula when mounted thereon, as the trocar pierces outwardly from the body cavity there is no escape of gas, which would collapse the cavity. This is particularly useful when a single external valve is used.
10

In one arrangement, the trocar is provided with an integral cutting element. This facilitates the cutting of the body cavity wall to allow introduction of the cannula.

Preferably, the trocar incorporates an extension shoulder, thereby allowing the trocar to
15 define a narrow incision, which is gently extended to ensure that the drawn cannula is firmly lodged in the body cavity wall preventing loss of gas from the cavity.

Preferably, the trocar incorporates guard means for protecting a surgeon's hand from being
20 cut when being introduced into the body cavity or as the device cuts the patients skin thereby preventing injury to the surgeon.

Preferably, the cannula incorporates means for attaching the cannula to an interior of the body cavity when in position.

25 Ideally, the means for attaching the cannula to an interior of the body cavity is provided by an internal distal ring.

In one arrangement, the internal distal ring and the cannula are integrally formed as a single unit.
30

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Preferably, the cannula incorporates one or more valves, internally or externally of the body cavity, to prevent loss of gas from the body cavity when the cannula is in position.

5 In one arrangement, the fixing means incorporates an anchor ring formed for releasable engagement with a proximal end of the cannula extending from the body when the cannula is in position in the body cavity. In this way, when the trocar has pierced the body cavity wall from within the cavity the portion of the cannula extending through the wall can be used to secure the cannula in position. This prevents tearing of the body tissue as the cannula is firmly attached to both internal and external walls of the body cavity.

10 Preferably, the anchor ring incorporates a thread for engaging on the same thread used to secure the trocar prior to installation of the cannula. This reduces the complexity of components and allows the threaded portion on the cannula to serve both functions.

15 In an alternative arrangement to that described above the valve is incorporated into the anchor ring.

In a particularly preferred embodiment of the invention the device incorporates an external seal and an internal valve, the seal and valve being mounted about opposing ends of the
20 cannula.

Preferably, the cannula is integrally formed with the seal and valve.

In one arrangement, the valve is integrally formed at one end of the cannula and has means
25 for releaseably engaging a seal housing at an opposing end.

Preferably, the seal housing incorporates a diaphragm seal.

In one arrangement, the seal housing defines an extended entry port.

30

Preferably, the entry port has a conical section.

- 5 -

In a preferred embodiment, the cannula incorporates an insufflation port. In this way the device may also incorporate the functionality required to inflate the body cavity in a single device. This ensures that the operating site is adequately and controllably inflated and that the component count is reduced, thereby, simplifying postoperative procedures.

5

Ideally, the insufflation port communicates with an insufflation lumen having insufflation ducts communicating between the port and the body cavity.

Preferably, the insufflation lumen is carried on an exterior surface of the cannula.

10

Preferably, the anchor ring incorporates finger grip means to facilitate engagement with the cannula.

15

Preferably, the anchor ring and or the distal ring incorporate cushion means to prevent trauma to the body cavity wall and ensure a gas tight seal.

20

In a particularly preferred arrangement, the device incorporates a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to insertion.

25

According to one aspect of the invention the device incorporates an adjustable pressure release valve. Thus, the surgeon may inflate the body cavity to a desired level and tenting or venting of additional gas added during surgery prevents tearing of tissue surrounding the incisions made. The surgeon is thereby assured of constant body cavity inflation.

30

According to another aspect of the invention there is provided a method for insertion of a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device being formed to allow insertion of medical equipment and comprising: -

a cannula defining a conduit into the body cavity;

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a trocar carried on the cannula and formed for piercing or cutting tissue to position the cannula; and

5 fixing means for removably securing the cannula in position on the patient during surgery,

the method comprising the steps of inserting the trocar into the body cavity through the access port, cutting or piercing tissue outwardly from within the body cavity using the
10 trocar out to an operating site and inserting a cannula in the incision made using the trocar.

According to another aspect of the invention, there is provided a surgical device for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device
15 being formed to allow insertion of medical equipment and comprising, a cannula defining a conduit into or out of the body cavity and fixing means for removably securing the cannula in position on the patient during surgery, the fixing means in turn comprising an inner seal and or an outer seal, the or each seal being movable along or about a longitudinal axis of the cannula to secure the device in position.

20

In one embodiment the fixing means is provided by:-

an inner seal having an upwardly extending conduit carried on an internal mounting ring; and

25

an external seal having an downwardly extending conduit carried on an external mounting ring,

30

the upwardly and downwardly extending conduits being formed for releasable engagement when in position on a patient to define the cannula.

Preferably, the conduits are formed for slidable interengagement.

- 7 -

Ideally, the conduits incorporate a ratchet retainer. This allows one conduit to be slid into position with one conduit being accommodated within the other and the ratchet ensures that the device can accommodate a wide variety of tissue wall widths while also
5 guaranteeing a suitable seal.

In one arrangement, the or each conduit is deformable to facilitate removal by disengaging the ratchet retainer.

10 Ideally, the, or each mounting ring has an associated pressure absorption and seal enhancement means, provided for example by a sponge.

In a particularly preferred embodiment, the cannula, when in position also incorporates a valve.

15 According to another aspect of the invention, the mounting rings are pivotally movable about the longitudinal axis. In this way the cannula may be positioned at an angle. This can allow a surgeon to position the cannula in such a way as to direct an inserted piece of equipment to an operating site or to facilitate insertion in a portion of the body cavity
20 where access is limited. Pivotal movement of the mounting rings ensures that seal integrity is maintained.

According to a still further aspect of the invention, the cannula is collapsible under pressure from one or both mounting rings to secure the cannula in position.

25 In one arrangement the cannula is provided by a section of pleated tubing carried on the cannula.

According to one aspect of the invention, the external mounting ring defines an entry
30 funnel having an oversize entry aperture for receiving and facilitating insertion of a piece of medical equipment.

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The invention will now be described more particularly with reference to the accompanying drawings, which show, by way of example only, an embodiment of a surgical device in accordance with the invention, in which:-

5 Fig. 1 is a perspective view of portion of a surgical device in accordance with the invention;

Fig. 2 is a sectional view of the surgical device of Fig. 1 in position on a patient;

10 Fig. 3 is a side view of the surgical device in accordance with the invention in a piercing position;

Fig. 4 is a side view of the device in a partially placed position;

15 Fig. 5 is a side view of the device in a pre-locking position;

Fig. 6 is a side view of the device shown in Figs. 3 to 5 in an in use position;

Figs. 7 and 8 illustrate operation of a valve for use with the invention;

20 Fig. 9 is a sectional view of an alternative embodiment of a surgical device in accordance with the invention in position on a patient;

25 Fig. 10 is a top view of portion of the device shown in Fig. 9 in the direction of the arrows X - X;

Fig. 11 is a sectional view of a further embodiment of a surgical device in accordance with the invention in position on a patient;

30 Fig. 12 is a top view of portion of the device shown in Fig. 11 in the direction of the arrows XII - XII;

Fig. 13 is a sectional view of a surgical device in accordance with the invention;

Fig. 14 is a sectional view of an alternative embodiment of a surgical device in accordance with the invention in position on a patient;

5

Fig. 15 is an enlarged sectional view of portion of the surgical device of Fig. 14;

Fig. 16 is a sectional view of a further alternative embodiment of a surgical device in accordance with the invention in an insertion position;

10

Fig. 17 is a sectional view of the surgical device of Fig. 16 in an in use position;

Fig. 18 is a sectional view of a still further alternative embodiment of a surgical device in accordance with the invention in an insertion position;

15

Fig. 19 is a sectional view of the device of Fig. 18 in an in use position;

Fig. 20 is a sectional view of a still further alternative embodiment of a surgical device in accordance with the invention;

20

Fig. 21 is a sectional view of a seal forming part of the invention;

Fig. 22 is an exploded view of discs forming part of the seal illustrated in Fig. 21;

25

Fig. 23 is a sectional view of an alternative seal forming part of the invention; and

Fig. 24 is a perspective view of the seal illustrated in Fig. 23.

Referring to the drawings, and initially to Figs. 1 to 8 there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1. The surgical device 1 is formed for use in minimally invasive surgery of the type using an inflated body cavity. The cavity is covered by in this case an abdominal wall 2 having an internal cavity

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wall 3 and an external wall 4. The internal cavity wall 3 is accessible to a surgeon through an access port (not shown)

In more detail, the device 1 has a trocar 5, a cannula 6 and an anchor ring 7. The trocar 5
5 has a cutting tip 8, a shoulder portion 9 and an internal thread (not shown) for connecting the trocar 5 to the cannula 6.

The cannula 6 has a threaded portion 12 for connection to the internal thread of the trocar 5 and for extending beyond the external wall 4 when in position. The cannula 6 also has a
10 body section 13 housing a valve 14 to prevent escape of gas from the body cavity when in position and an integrally formed distal ring 15 for engaging the internal wall 3.

The anchor ring 7 has an internal threaded portion 17 formed for engagement with the cannula threaded portion 12 and finger grip means 18 for facilitating this engagement.
15

In use, and referring now in particular to Figs. 3 to 6 the device 1 is inserted into the body cavity. The trocar 5 is moved into a piercing position as shown in Fig.3 with cutting tip 8 in contact with the inner wall 3. The cutting tip 8 is then pressed through the abdominal wall 2 until the tip 8 and shoulder portion 9 extends beyond the external wall 4. When the
20 distal ring 15 comes into contact with the internal wall 3 and the body section 13 is in the abdominal wall 2 the trocar 5 is unscrewed from the threaded portion 12 of the cannula 6. (See Fig. 4.)

The anchor ring 7 is then ready for engagement as shown in Fig. 5. The finger grip means
25 18 are used to engage the threaded portion 17 with the threaded portion 12 of the cannula 6 until the anchor ring 7 is firmly pressed against the external wall 4. (See Figs. 2 and 6)

The invention provides a simple method and device which prevents accidental damage to the patients tissue or organs by ensuring that the cutting or piercing point of the trocar is
30 directed away from the patient's body during insertion. This is achieved in a way that ensures that the cannula is automatically drawn into position.

It will be understood that the cutting or piercing method may optionally include the use of an energy source such as a heater or spring-loaded mechanism for executing the cut using a minimum of force.

5

To avoid unnecessarily obscuring the present invention, detailed description of the valve has not been included, as it will be apparent to those skilled in the art that a wide variety of valves may be successfully employed. One such possibility is a twist valve, but any suitable valve may be used.

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Referring now to Figs. 7 and 8 there is illustrated one example of a valve for use with the device indicated generally by the reference numeral 700 in which parts illustrated in Figs. 1 to 6 are indicated by the same numerals generally. With the device in position the valve 700 is located within the body cavity. A pair of doors 701 hingedly connected to the cannula 6 provides the valve. The doors 701 are biased into a closed position by a rubber cover 702. When a surgical implement 703 is inserted into the cannula (See Fig. 8) the doors 701 are forced outwardly against the cover 702. The cover 702 seals around the surgical implement 703 preventing escape of air from the cavity and as the implement is removed they also act to close the doors 701.

20

Referring now to Figs. 9 and 10 there is illustrated a further embodiment of a surgical device indicated generally by the reference numeral 900 in which parts similar to those described with reference to Figs. 1 to 8 are identified by the same numerals generally.

In this embodiment, the device 900 incorporates a releaseably attachable external seal housing 901 and an internal one way valve 902 mounted about opposing ends of the cannula 6. The housing 901 is located on the cannula 6 when in position on the patient using O rings 905. The housing 901 incorporates a diaphragm seal 903 and defines an outwardly directed extended entry port indicated at 904. The entry port 904 has a conical

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section and is so formed to facilitate insertion of a surgical device by directing the device to the cannula 6. The housing 901 also defines an insufflation port 910 for receiving insufflation gases. These gasses are routed to the body cavity to ensure adequate and controlled inflation through insufflation ducts 911 carried in an insufflation lumen 912.

- 5 The lumen 912 is carried on an exterior surface of the cannula 6 and terminates at the one way valve 903 with an insufflation outlet 913.

In use, the device 900 is positioned on the patient substantially as described with reference to Figs. 1 to 8. When the cannula 6 is in position the housing 901 is fixed in position using
10 the O rings 905. The body cavity may then be inflated. A gas source (not shown) is connected with a pipe to the insufflation port 910. The gas is routed to the body cavity through the insufflation ducts 911 of the insufflation lumen 912 and out into the cavity through the insufflation outlet 913.

- 15 Once inflated instruments are passed through the diaphragm seal 903 to enter the cannula 6 having first been introduced and guided into position by a tapering internal surface of the entry port 904. Instruments are then passed down the cannula 6 and into the inflated body cavity through the one way valve 902.

- 20 It will be understood that a cannula sheath separated from the cannula body and running along the cannula exterior may equally provide the insufflation lumen.

Referring now to Figs. 11 and 12 there is illustrated a further embodiment of a surgical device indicated generally by the reference numeral 1100 in which parts similar to those
25 described with reference to Figs. 1 to 10 are identified by the same numerals generally.

- In this embodiment, the cannula 6 terminates in the body cavity with a one way valve 1101. Compressing a thin sleeve 1102 between two semi-circular, flexible foam pieces 1103 forms the valve 1101. The valve allows for the insertion of surgical implements and
30 prevents the escape of gas from the body cavity.

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It will be noted that while threaded engagement of the component parts of the device is described throughout any suitable method of engagement is acceptable.

It will also be noted that the distal ring and anchor ring may be suitably coated with
5 airtight, antiseptic and or shock absorbent material to prevent trauma to the abdominal wall and loss of gas from the body cavity.

It will be understood that the anchor ring may be extended to incorporate a valve, which allows insertion of instruments thereby reducing the weight of the device.

10 It will also be understood that the device may incorporate a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to insertion.

15 It will further be understood that the device may incorporate an adjustable pressure release valve. This will allow the surgeon to inflate the body cavity to a desired level and ensure a constant level of body cavity inflation by continuously supplying inflation gas and venting any excess through the pressure release valve. This prevents excessive movement of the cavity wall during the procedure, which can inconvenience the surgeon and cause trauma
20 to the patient

Referring to the drawings again and now to Fig. 13 there is illustrated a surgical device according to the invention, indicated generally by the reference numeral 1300. The surgical device 1300 is formed for use in minimally invasive surgery of the type using an
25 inflated body cavity. The cavity is covered by in this case an abdominal wall 1302 having an internal cavity wall 1303 and an external wall 1304. The internal cavity wall 1303 is accessible to a surgeon through an access port (not shown)

In more detail, the device 1300 has a fixing means provided by an inner sealing ring 1330
30 and an outer sealing ring 1340. The outer ring 1340 is movable along a longitudinal axis of a cannula 1320 to secure the device 1300 in position on the abdominal wall 1302. The cannula 1320 is defined by the interengagement of an upwardly extending conduit 1331

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carried on the ring 1330 and a downwardly extending conduit 1341 carried on the ring 1340. The conduit 1341 has a ratcheted retainer exterior surface portion (not shown) and is dimensioned to slidably engage and ratchet within the conduit 1331 against a ratcheted interior portion thereof (not shown). Once engaged the conduits 1331 and 1341 define the cannula 1320. This form of engagement allows the device 1300 to accommodate a wide variety of walls 1302 while also guaranteeing a suitable seal. The outer ring 1340 has an absorbent sealing sponge 1342. The inner sealing ring 1330 also has a sponge 1332 and a valve 1343 to prevent escape of gas from the cavity.

In use, the device 1300 is inserted into the body cavity by first introducing the inner sealing ring 1330 into the cavity and pushing the conduit 1331 through the wall 1302. Pushing continues until the sponge 1332 comes into contact with the internal cavity wall 1303. The ring 1340 is then positioned over the conduit 1331 with the conduit 1341 extending downwards. The conduit 1341 is then introduced into the conduit 1331 and slideably engaged. Sliding continues until the sponge 1342 presses snugly against the external wall 1304. The device is securely held as the ratcheted portions of the conduits ensure positive contact. The valve 1343 prevents gas from escaping during an operation.

Referring now to Figs. 14 and 17 there is shown an alternative device indicated generally by the reference numeral 2000 in which parts shown in Fig. 13 are identified by the same reference numerals generally. The device 2000 in use operates in a similar fashion but in this embodiment a conduit 1410 is greatly shortened over the conduit 1331 of Fig. 13. A conduit 1310 in this instance has a ratcheted surface 1330 along an exterior portion. A ratchet retainer is provided by the slidable engagement of the surface 1330 against a grip 2010 carried on the ring 1340.

Release of the device 2000 is effected in this instance by squeezing the grip 2010 toward the conduit 1310 to disengage the grip 2010 from the surface 1330.

Referring now to Figs. 16 and 17 there is shown a further embodiment of a device indicated generally by the reference numeral 4000 in which parts shown in Fig. 13 are identified by the same reference numerals generally. The device 4000 has an internal ring

- 15 -

4300 and an external ring 4400 pivotally mounted on a cannula 4200. Engagement of the device 4000 and the rings 4300 and 4400 is similar to that described above. In this embodiment the pivotal movement of the rings about the longitudinal axis of the cannula 4200 allows the cannula to be inserted at an angle. As the ring 4300 approaches the
5 internal wall 1330 the pivotal movement allows the ring 4300 to move to contour the internal wall 1303. Similarly the external ring 4400 moulds the external wall 1304. This movement allows a surgeon to position the cannula in such a way as to direct an inserted piece of equipment to an operating site or to facilitate insertion in a portion of the body cavity where access is limited. Pivotal movement of the mounting rings also ensures that
10 seal integrity is maintained.

Referring now to Figs. 18 and 19 there is shown a further embodiment of a device indicated generally by the reference numeral 5000 in which parts shown in Fig. 13 are identified by the same reference numerals generally. In this embodiment, the cannula 1320
15 incorporates a pleated tubing 5500. As the ring 1340 is positioned, the trocar 1350 is removed and the cannula 5500 is collapsed. This collapse causes the cannula 5500 to expand and provides an additional seal around the body incision.

Now referring to Fig. 20 there is shown a further embodiment of a device indicated
20 generally by the reference numeral 8000. In this embodiment the ring 8400 defines a funnel entry 8450 to facilitate insertion of medical instruments. This embodiment also has a foam spacer 8460 which is particular useful when it is desired to extend the cannula.

It is envisaged that the cannula may incorporate a deformable web, such as corrugated
25 tubing, which will deform when in position on a patient to stabilise the cannula and to provide a seal.

It will be understood that the device may include a number of seals and that these seals may operate independently or in combination. For example, the device may include a seal
30 adjacent the outer ring which will engage only when an instrument has been passed into the body cavity and there is a risk of gas escaping from a seal adjacent the inner sealing ring.

Referring now to Figs. 21 and 22, there is illustrated one such seal forming part of the invention indicated generally by the reference numeral 9000. The seal 9000 has a locking ring 9010, a diaphragm seal 9020 and two slit seals 9030, 9040. The slit seals 9030, 9040 each have four orthogonally arranged slits 9050 radiating from the center and the seals 9030, 9040 are offset by forty five degrees. In use, a seal is provided as an instrument is introduced by the action of pressing the instrument against the slits 9050. When the device is removed, the slits 9050 return to normal resting position offset by forty five degrees from the slit above thereby maintaining an overall seal.

- 10 Figs. 23 and 24 show a similar seal to that illustrated in Figs. 21 and 22 illustrated generally by the reference numeral 9500. In this seal 9500 the slits 9050 are orthogonally directed as before on a concave disc 9510. The concave nature of the disc 9510 ensures that the slits 9050 are pressed together. Upward movement beyond a resting position of any portion of the disc 9510 is prevented by the provision of four webs 9511 on the
- 15 underside of the disc 9510 intermediate the slits 9050.

- It will be noted that the invention is directed to wards providing a reduced trauma, low profile, airtight cannula. It will be appreciated also that the device is particularly suited for use with a trocar and is ideal for applications in which the device is positioned from within the body cavity. Thus, the invention provides a simple method and device which prevents accidental damage to the patients tissue or organs by ensuring that the cutting or piercing point of the trocar is directed away from the patient's body during insertion.
- 20

- It will be understood that the cutting or piercing method may optionally include the use of an energy source such as a heater or spring-loaded mechanism for executing the cut using a minimum of force.
- 25

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To avoid unnecessarily obscuring the present invention, detailed description of the valve has not been included, as it will be apparent to those skilled in the art that a wide variety of valves may be successfully employed. One such possibility is a twist valve, but any suitable valve may be used.

5

It will be noted that the external ring may define a circular entry port or a partial funnel with an oversized opening to facilitate threading of components into the cannula.

10 It will also be noted that the internal and external rings may be suitably coated with airtight, antiseptic and or shock absorbent material to prevent trauma to the abdominal wall and loss of gas from the body cavity.

It will be understood that the anchor ring may be extended to incorporate a valve, which allows insertion of instruments thereby reducing the weight of the device.

15

It will also be understood that the device may incorporate a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to insertion.

20 It will further be understood that the device may incorporate an adjustable pressure release valve. This will allow the surgeon to inflate the body cavity to a desired level and ensure a constant level of body cavity inflation by continuously supplying inflation gas and venting any excess through the pressure release valve. This prevents excessive movement of the cavity wall during the procedure, which can inconvenience the surgeon and cause trauma
25 to the patient

It will be noted that the devices described herein may be provided as modular devices and that the device may be formed to accommodate different sizes of seals and valves to allow the device a broad scope of application.

30

It will also be noted that the device may optionally include an insufflation lumen or conduit to provide pneumoperitoneum at the operating site.

It will also be understood that the component parts of the device may be transparent to facilitate a surgeon during the course of an operation.

- 5 It will of course be understood that the invention is not limited to the specific details described herein, which are given by way of example only, and that various modifications and alterations are possible within the scope of the invention as defined in the appended claims.

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CLAIMS:

1. A surgical device (1) for use in minimally invasive surgery of the type where a body cavity is inflated to be accessible to a surgeon through an access port surrounding an incision in a patient's body, the device (1) being formed to allow insertion of medical equipment and comprising: -

a cannula (6) defining a conduit into the body cavity;

a trocar (5) carried on the cannula (6) and formed for piercing or cutting tissue to position the cannula (6); and

fixing means (7) for removably securing the cannula (6) in position on the patient during surgery,

characterised in that the trocar (5) is removably mounted on the cannula (6), with the trocar (5) providing a gas-tight cap for the cannula when the trocar is mounted on the cannula thereby enabling the trocar (5) to be inserted into the body cavity through the access port and to cut or pierce tissue outwardly from within the body cavity out to an operating site, with no escape of gas from the body cavity.

2. A surgical device as claimed in claim 1, wherein the trocar (5) and cannula (6) are removably mounted with complementary engageable short threads (12).
3. A surgical device (1) as claimed in claim 1 or claim 2, wherein the trocar (5) is provided with an integral cutting element (8), thereby facilitating the cutting of the body cavity wall (2) to allow introduction of the cannula (6).
4. A surgical device (1) as claimed in claim 3, wherein the trocar (5) incorporates an extension shoulder (9).

20

5. A surgical device (1) as claimed in any preceding claim, wherein the trocar (5) incorporates guard means for preventing injury to the surgeon.
6. A surgical device (1) as claimed in any preceding claim, wherein the cannula (6) incorporates means (15) for releaseably attaching the cannula to an interior (3) of the body cavity.
7. A surgical device as claimed in claim 6, wherein the means (15) for attaching the cannula (6) to an interior (3) of the body cavity is provided by an internal distal ring(15).
8. A surgical device (1) as claimed in claim 7, in which the internal distal ring (15) and the cannula (6) are integrally formed as a single unit.
9. A surgical device (1) as claimed in any preceding claim, wherein the cannula (6) incorporates a valve to prevent loss of gas from the body cavity when the cannula is in position.
10. A surgical device as claimed in any preceding claim, wherein the fixing means incorporates an anchor ring (7) formed for releasable engagement with a proximal end of the cannula (6) extending from the body when the cannula (6) is in position in the body cavity.
11. A surgical device as claimed in claim 10, wherein the anchor ring (7) incorporates a thread for engaging on the same thread (12) used to secure the trocar (5) prior to installation of the cannula (6).
12. A surgical device as claimed in claim 10 or 11, wherein the anchor ring (7) incorporates a valve.
13. A surgical device as claimed in any preceding claim, incorporating an external seal (901) and an internal valve (902), the seal (901) and valve (902) being mounted about opposing ends of the cannula (6).

AMENDED SHEET

14. A surgical device as claimed in claim 13, wherein the cannula (6) is integrally formed with the seal (901) and valve (902).
- 5 15. A surgical device as claimed in claim 13 or 14, wherein the valve (902) is integrally formed at one end of the cannula (6) and has means (905) for releaseably engaging a seal housing (901) at an opposing end.
- 10 16. A surgical device as claimed in claim 15, in which the seal housing (901) incorporates a diaphragm seal.
17. A surgical device as claimed in any of claims 13 to 16, wherein the seal housing (901) defines an extended entry port (904).
- 15 18. A surgical device as claimed in claim 17, wherein the entry port (904) has a conical section.
19. A surgical device as claimed in any preceding claim, wherein the cannula (6) incorporates an insufflation port (910).
- 20 20. A surgical device as claimed in claim 19, in which the insufflation port (910) communicates with an insufflation lumen (912) having insufflation ducts (911) communicating between the port (910) and the body cavity.
- 25 21. A surgical device as claimed in claim 20, wherein the insufflation lumen (912) is carried on an exterior surface of the cannula (6).
22. A surgical device as claimed in any of claims 11 to 21, wherein the anchor ring (7) incorporates cushion means to prevent trauma to the body cavity wall and ensure a gas
- 30 tight seal.

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23. A surgical device as claimed in any of claims 11 to 22, wherein the distal ring (15) incorporates cushion means to prevent trauma to the body cavity wall and ensure a gas tight seal.

5 24. A surgical device as claimed in any preceding claim, incorporating a detachable security retainer formed for engagement with a surgeon's hand or instrument to prevent loss of the device in the cavity prior to being fixed in position on a patient.

10 25. A surgical device as claimed in any preceding claim, incorporating an adjustable pressure release valve.

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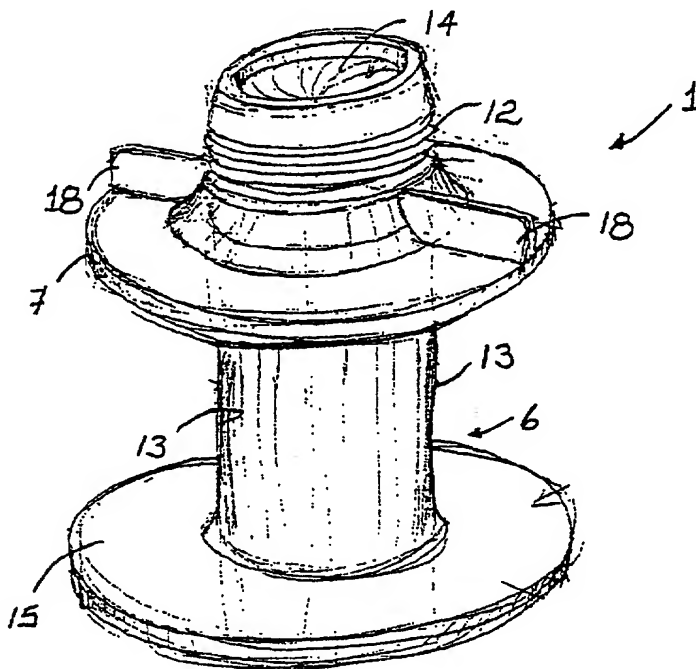
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(75) Inventors/Applicants (*for US only*): CALDWELL, Martin [IE/IE]; 37 Mount Pleasant Square, Ranelagh, Dublin

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

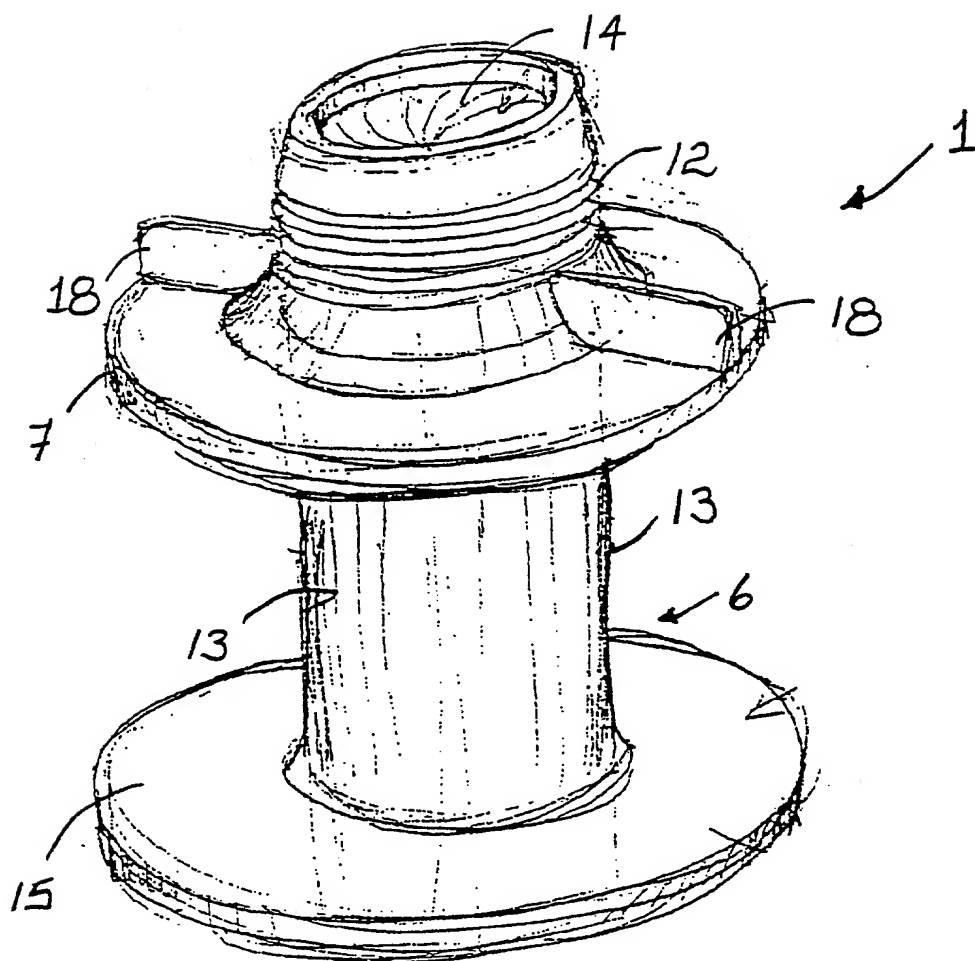
(54) Title: A SURGICAL DEVICE



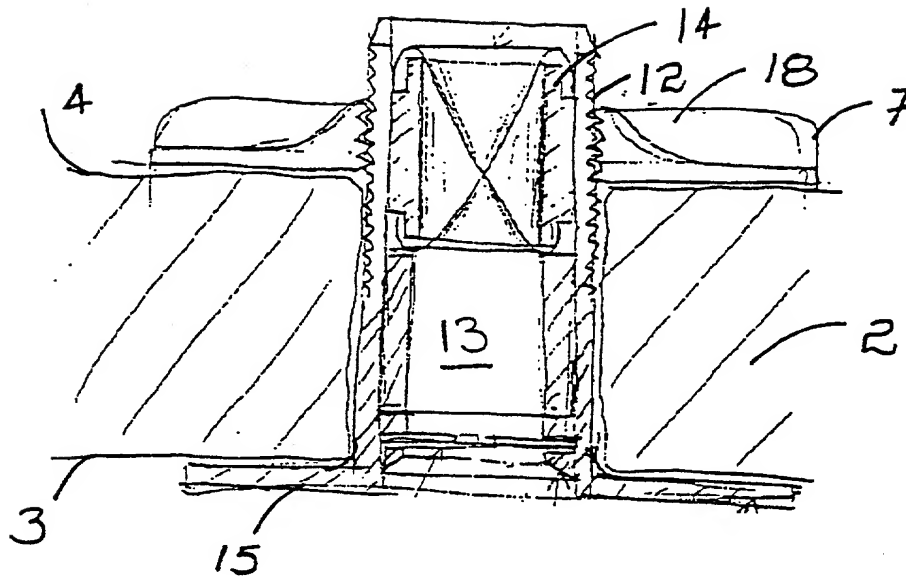
(57) Abstract: A surgical device (1) for use in minimally invasive surgery is inserted into a body cavity. A trocar (5) is moved into a piercing position with a cutting tip (8) in contact with an inner wall (3) before the cutting tip (8) is pressed through the abdominal wall (2). When in position, the trocar (5) is unscrewed from a cannula (6) and the device (1) is secured with an anchor ring (7). The device (1) which prevents accidental damage to the patients tissue or organs by ensuring that the cutting or piercing point of the trocar (5) is directed away from the patient's organs during insertion.

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Fig. 1

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Fig. 2

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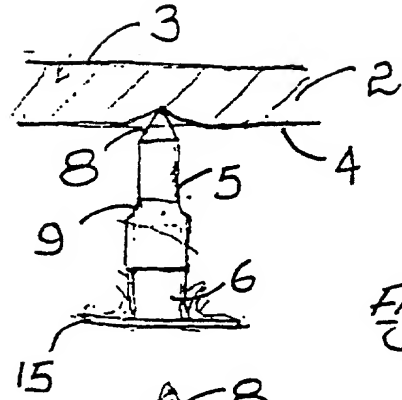


Fig. 3

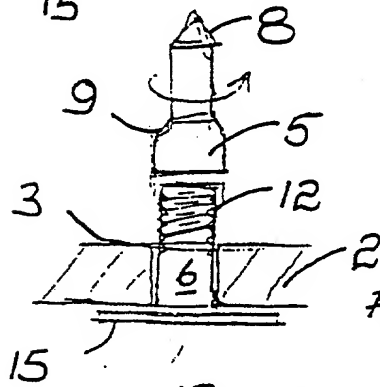


Fig. 4



Fig. 5

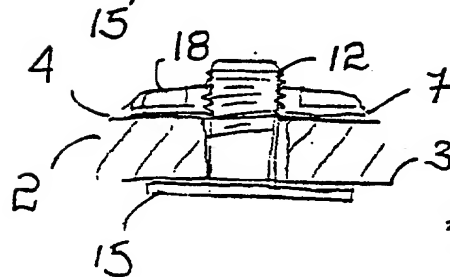
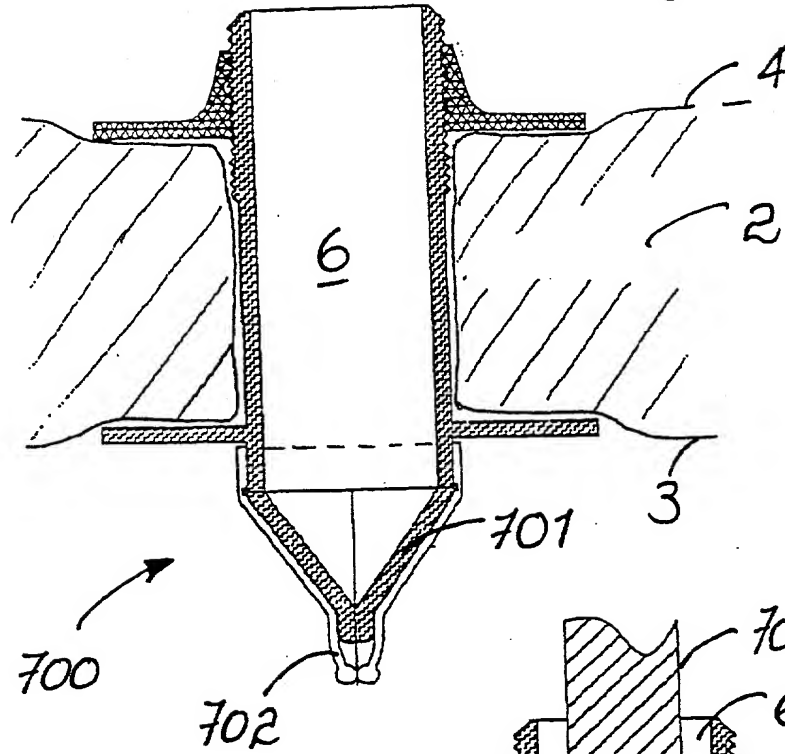
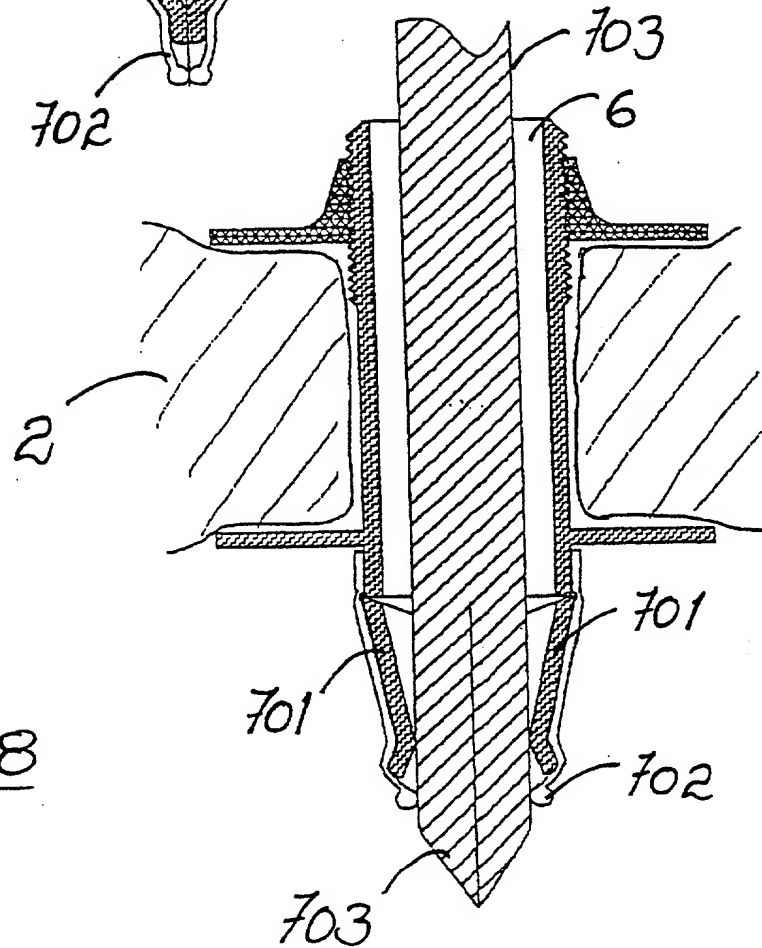
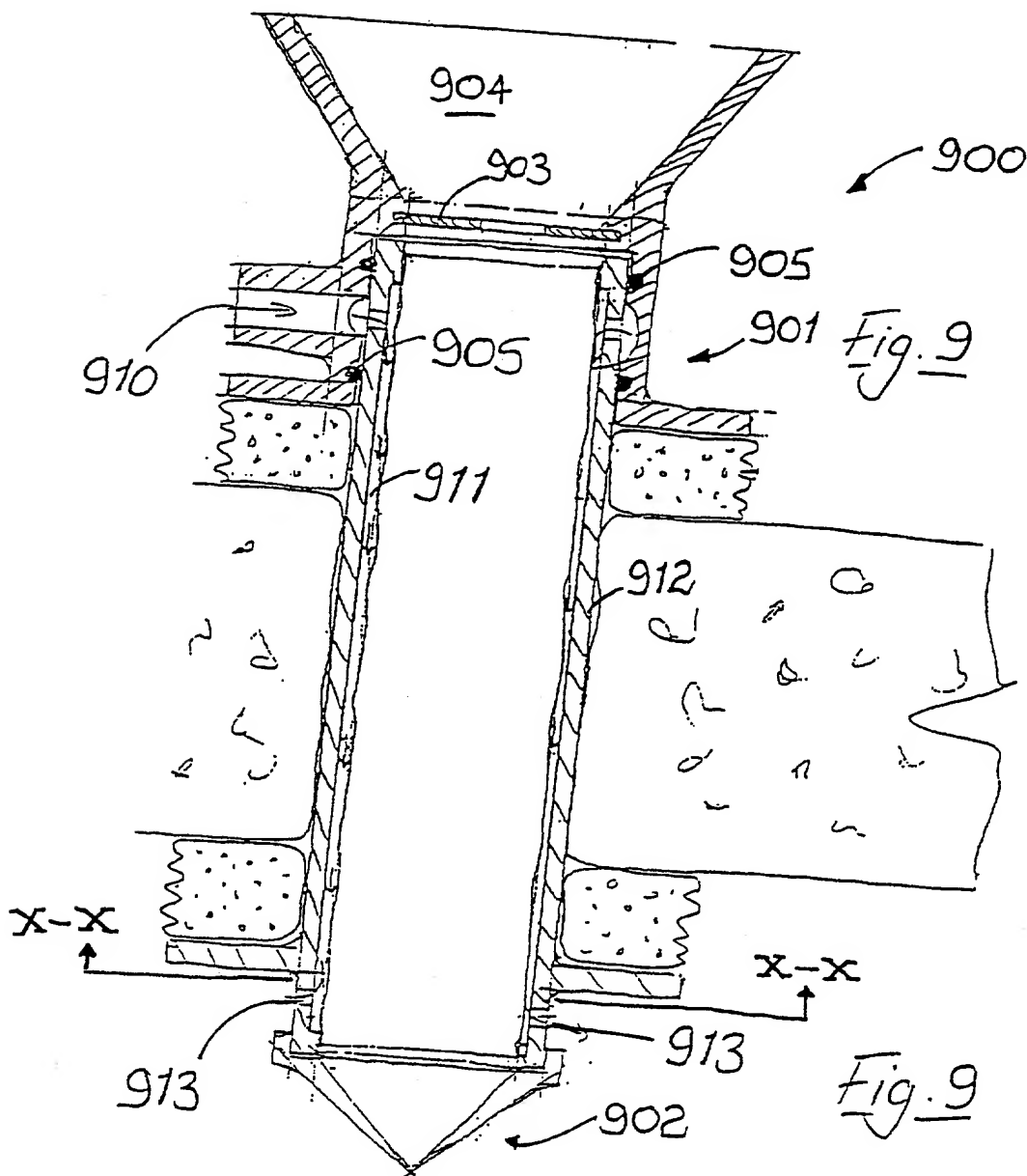
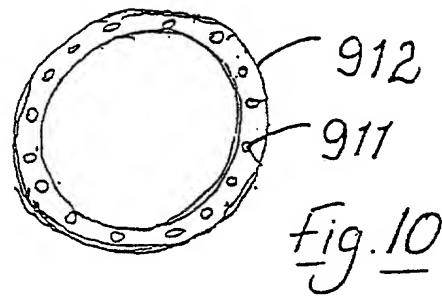


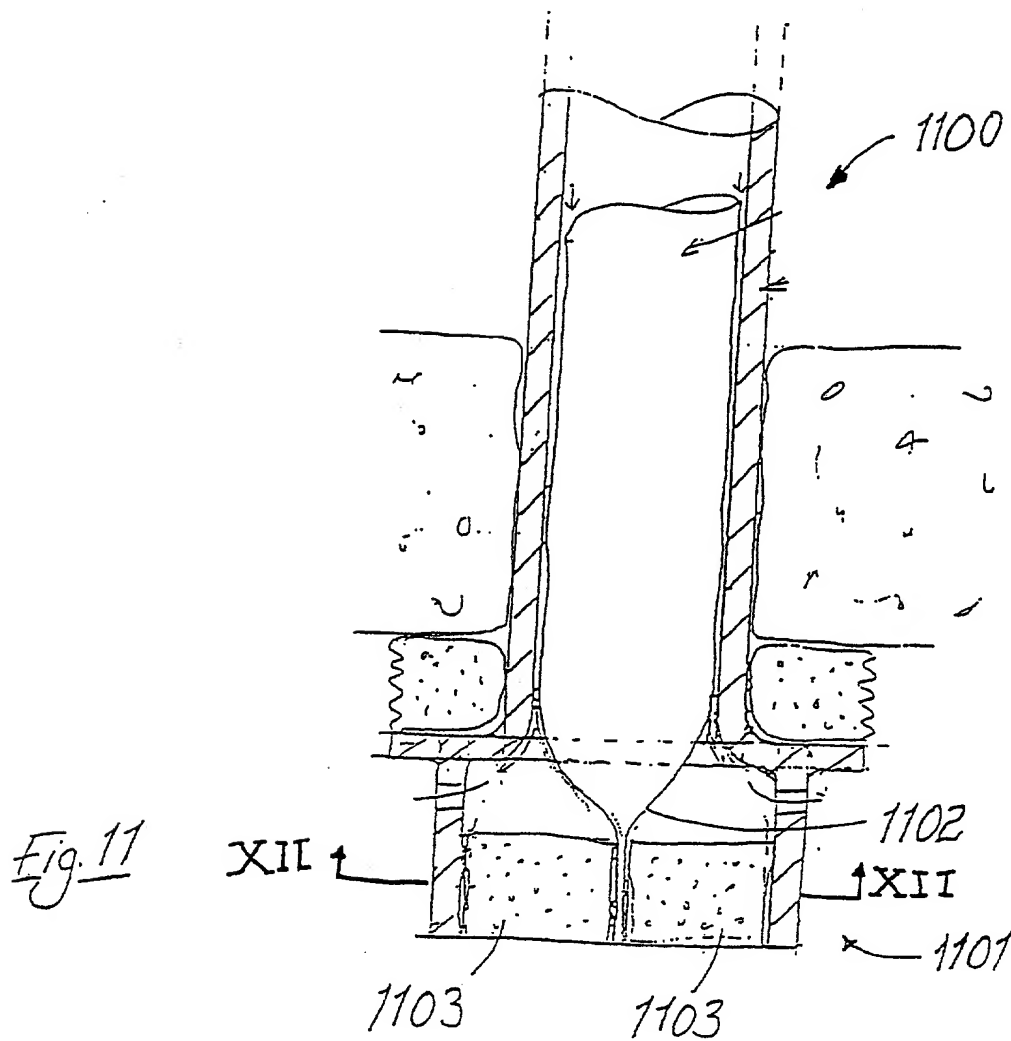
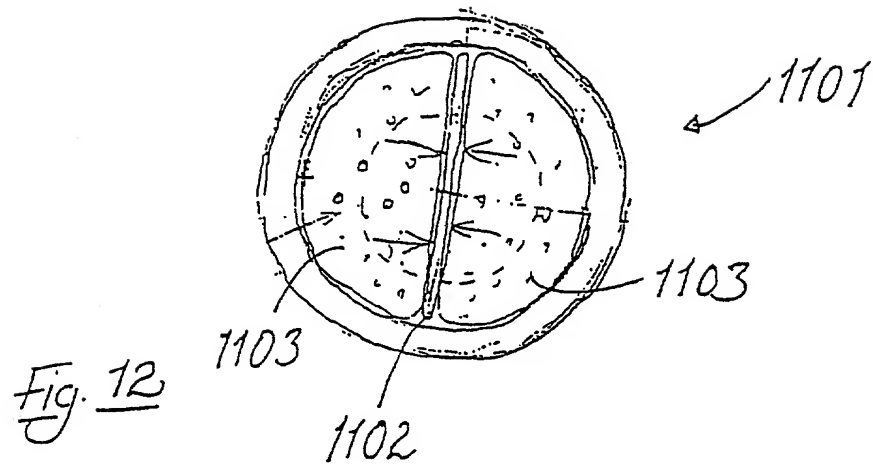
Fig. 6

Fig. 7*Fig. 8*

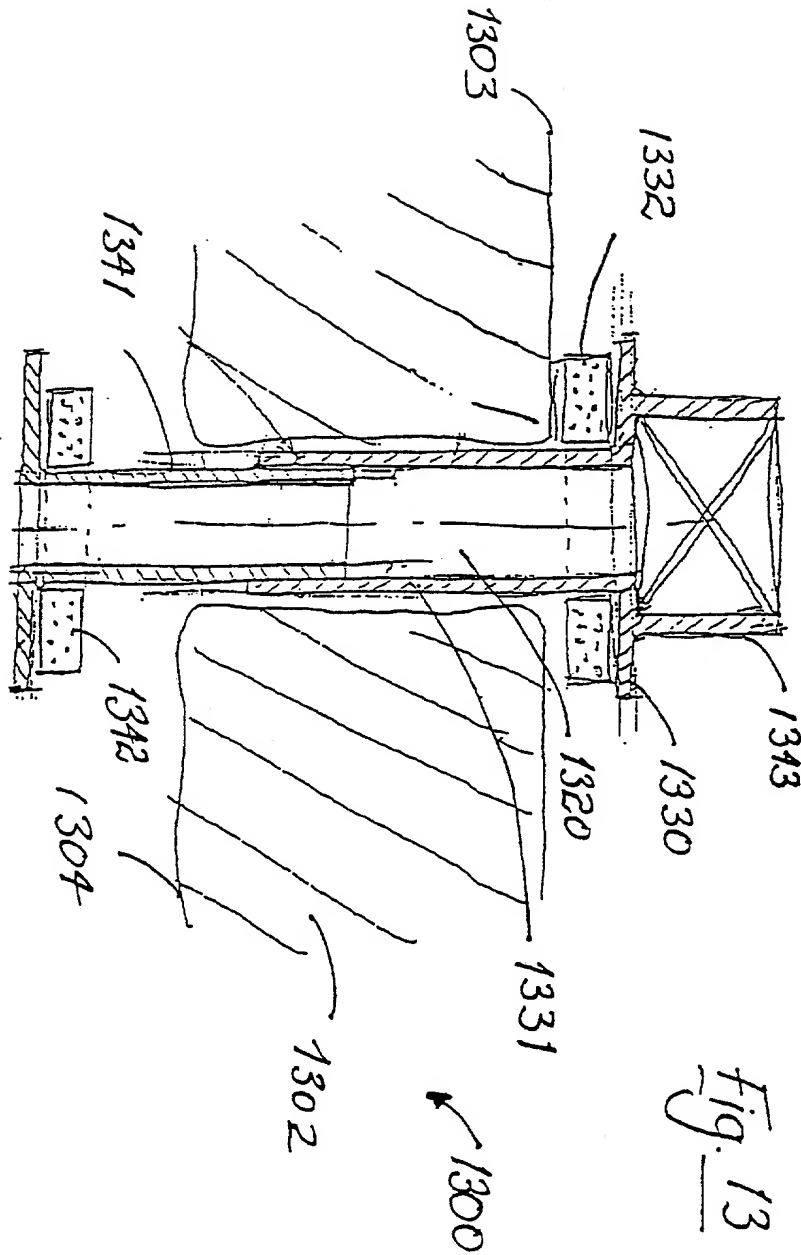
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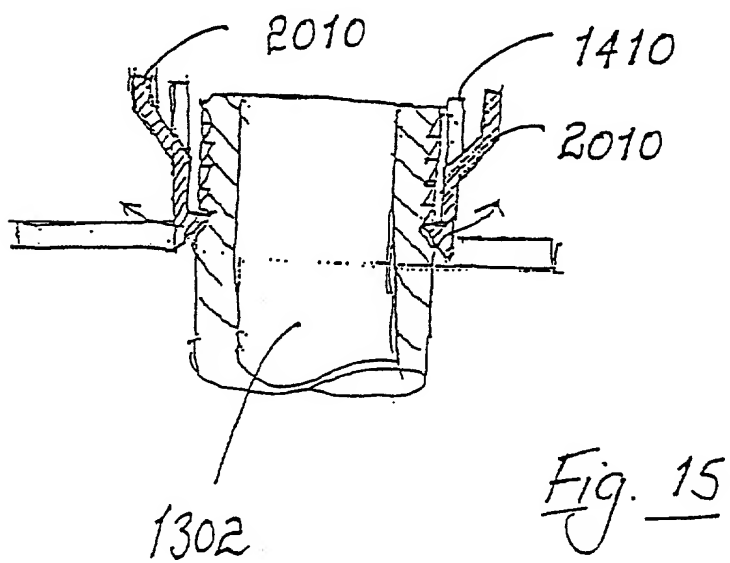
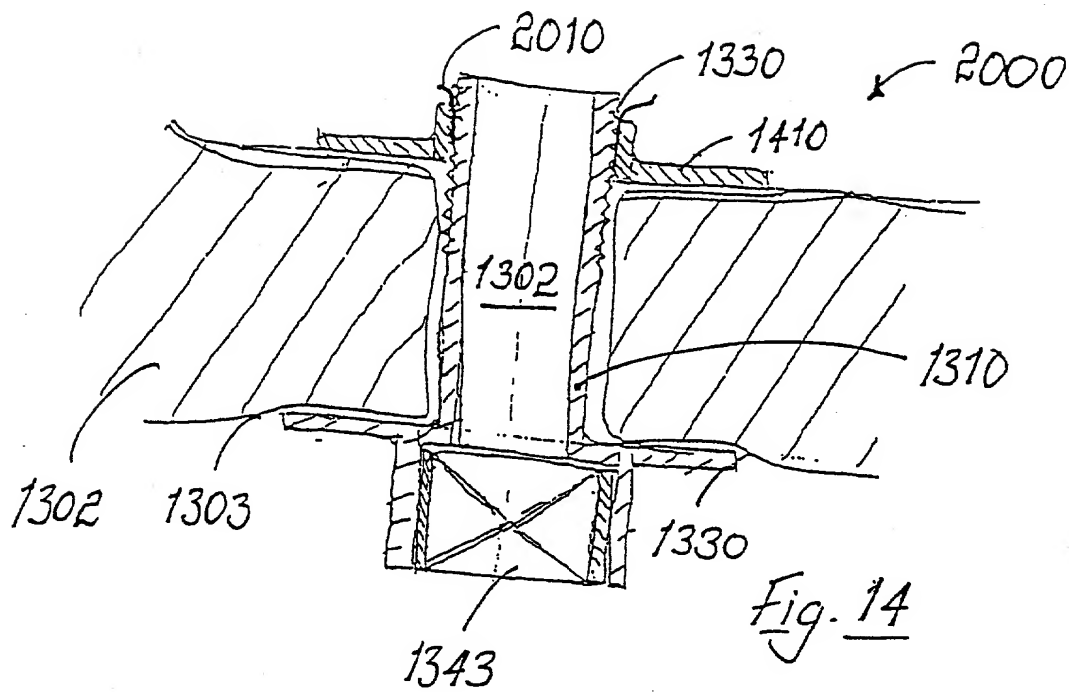
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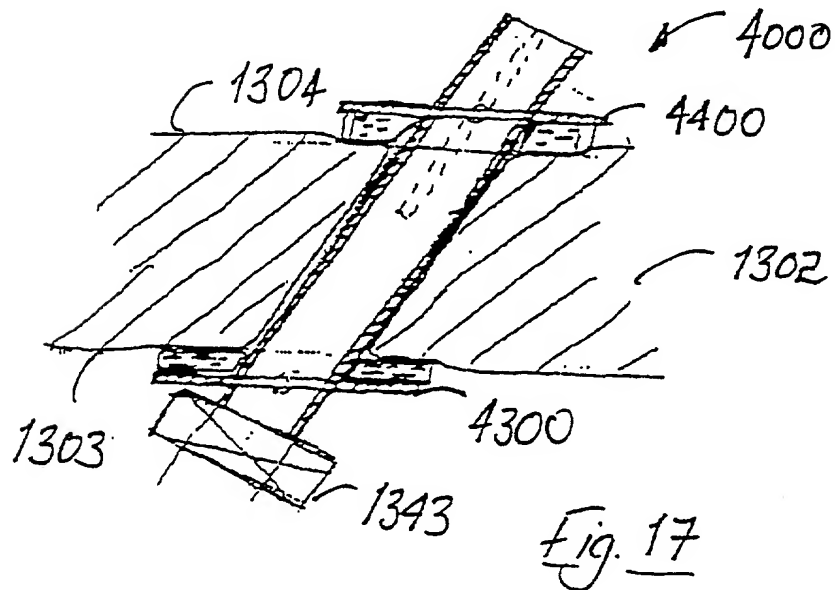
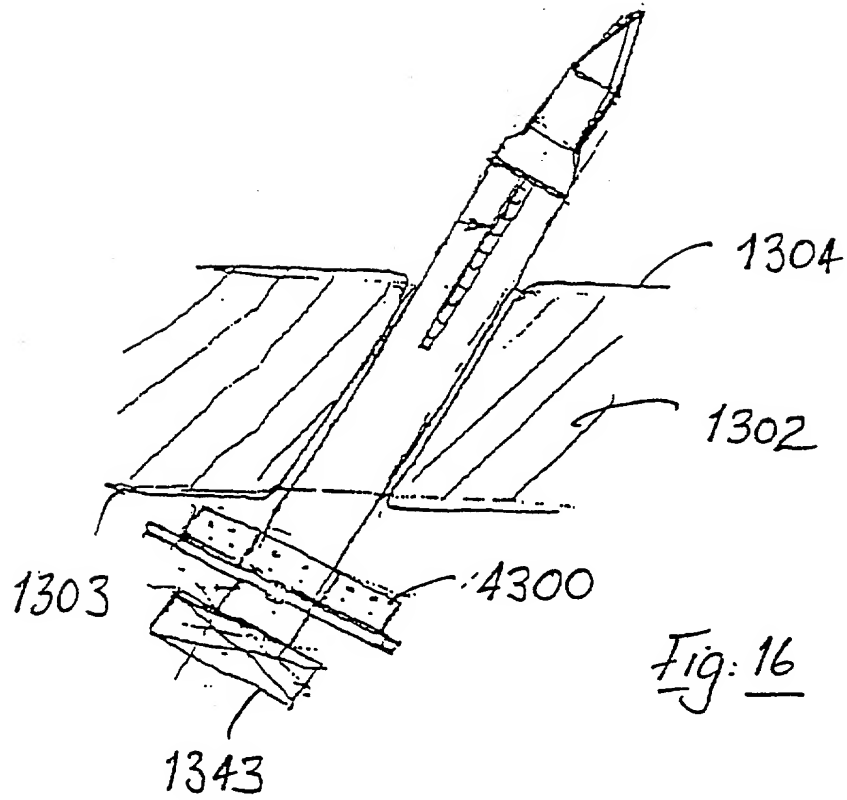
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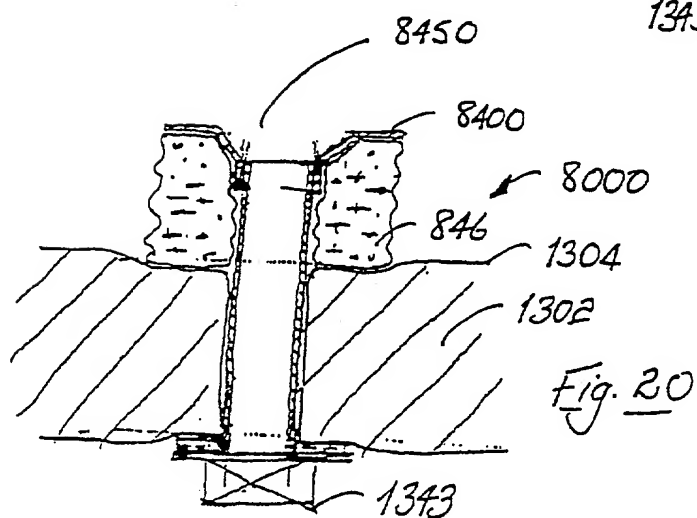
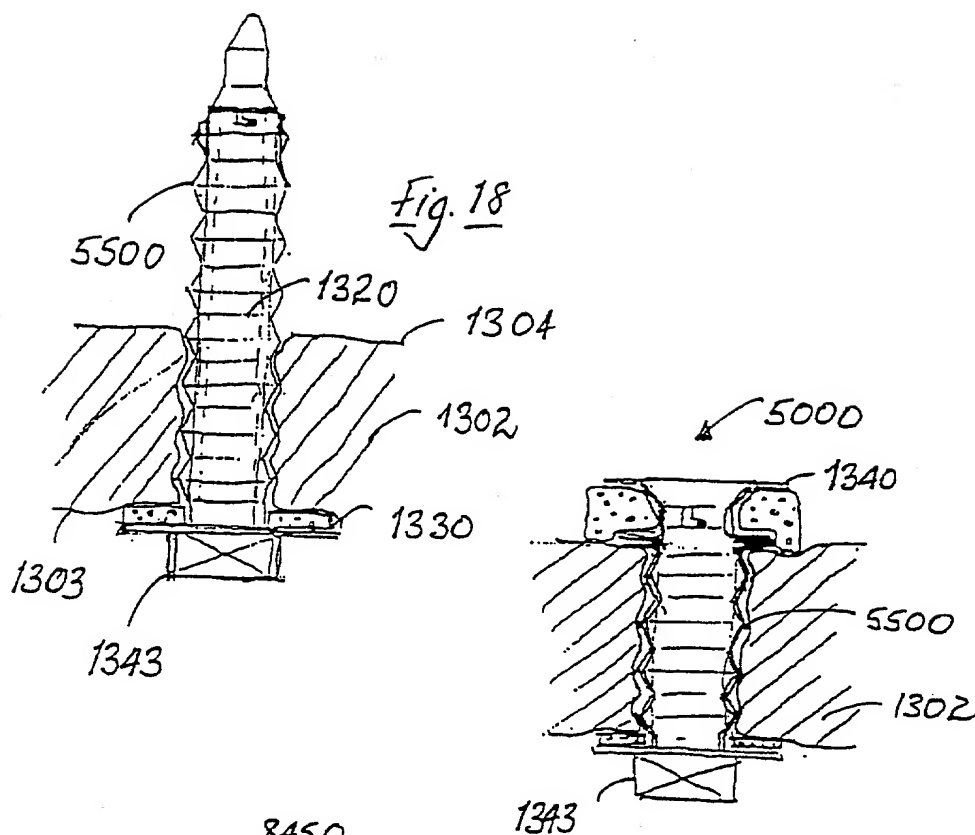
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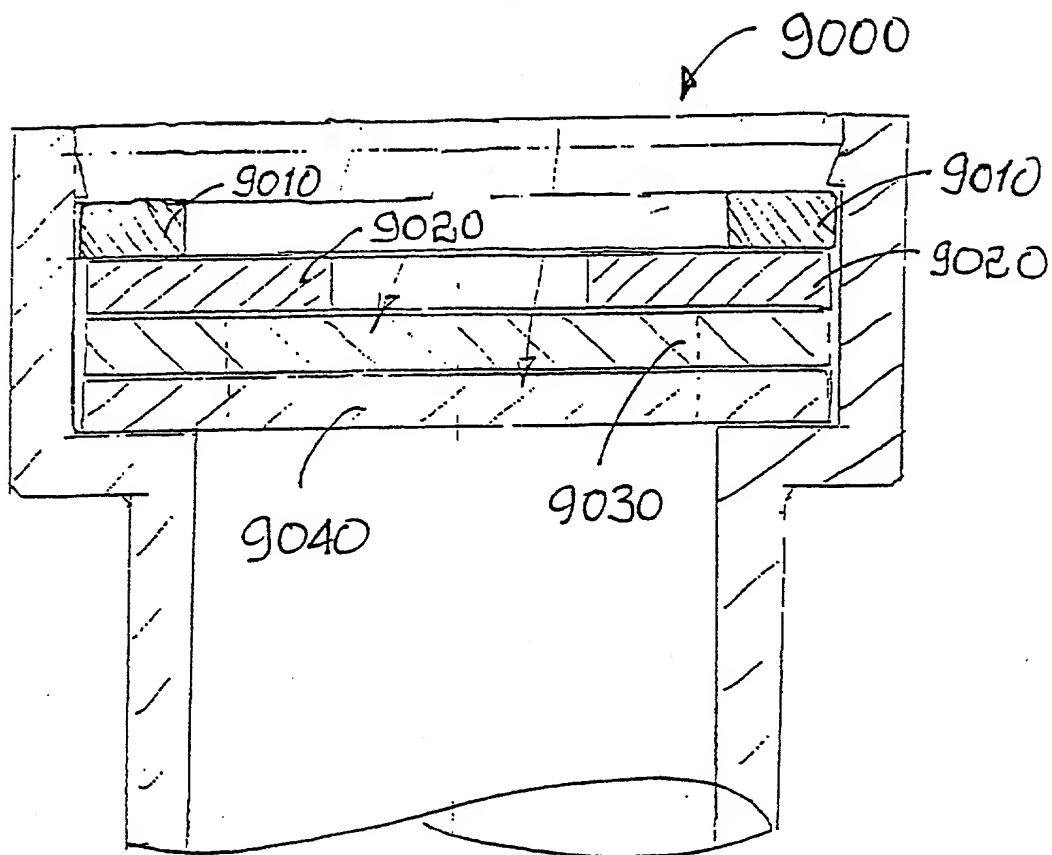


Fig. 21

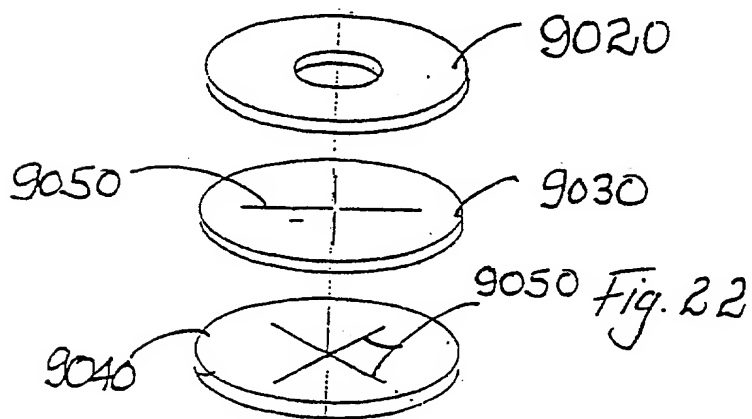


Fig. 22

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Fig. 23

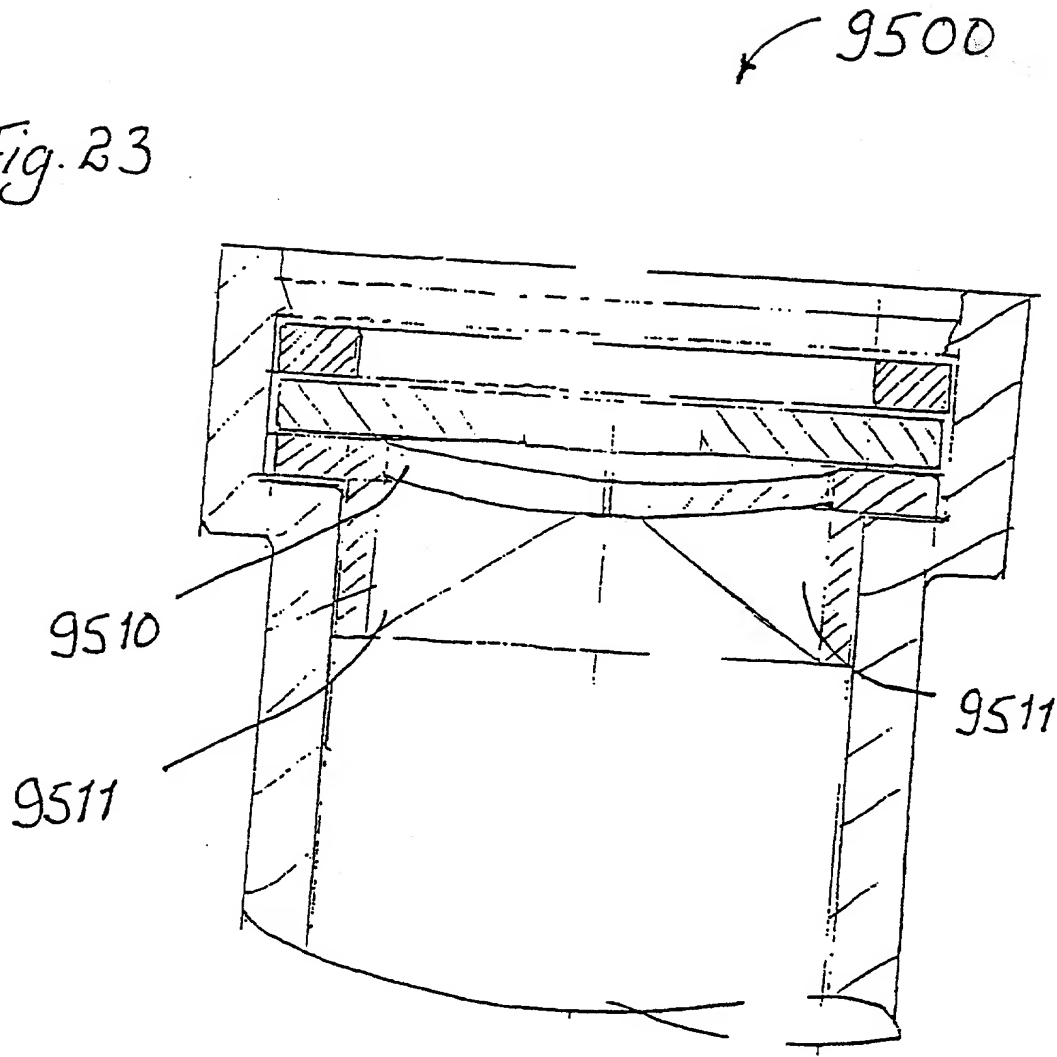
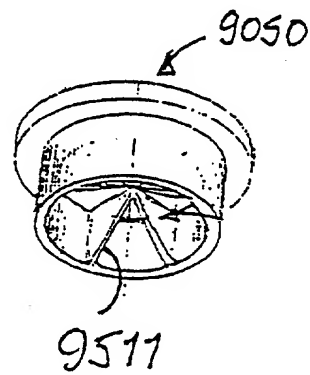


Fig. 24



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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)

As the below named inventor(s), I/we declare that:

Martin CALDWELL, Christy CUMMINS

This declaration is directed to:

☐ The attached application, or

☒ Application No. PCT/IE00/00093 on 28th July 2000

☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including material information which became available between the filing date of the prior application and the National or PCT International filing date of the continuation-in-part application, if applicable; and

All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

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Signature: _____

Citizen of: _____

☐ Additional inventors are being named on _____ additional form(s) attached hereto.

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